Docket No. 101896-890 (DEP6088USPCT)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Roque Humberto Ferreyro et al.	
Application No:	10/549,409	Conf. No. 1699
Filing Date:	September 14, 2005	Group Art Unit: 3775
Entitled:	HYDRAULIC DEVICE FOR THE INJECTION OF BONE CEMENT IN PERCUTANEOUS VERTEBROPLASTY	Examiner: Sameh R. Boles

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being filed via EFS-Web on the date shown below.

Dated: July 25, 2011 Signature: _____ (Ronald E. Cahill)

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APPEAL BRIEF PURSUANT TO 37 C.F.R.§41.37

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine, Inc. of Raynham, Massachusetts derives its rights in this application by virtue of an assignment of the application from the prior assignee, Disc-O-Tech Medical Technologies Ltd to DePuy Spine, Inc. as recorded at Reel 020370, Frame 0879.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 8, 12, 20, 36-39, 50, 51, 59-61 and 78 are currently pending and stand rejected in the present application. Claim 60 has been withdrawn, and claims 1-7, 9-11, 13-19, 21-35, 40-49, 52-58, 62-77 were previously canceled. Claims 8, 12, 20, 36-39, 50, 51, 59, 61 and 78 stand rejected, and are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments were made after the final Office Action, which was mailed on June 25, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention relates to surgical procedures, including vertebroplasty and kyphoplasty, which require injecting a dense or viscous fluid through a needle. More specifically, the claimed invention is an improved method of delivering viscous bone cement material under fluoroscopy to a site in a patient. Claims 37 and 78 are the only independent claims.

Independent claim 37 recites a method of delivering a viscous material under fluoroscopy to a site in a patient. A delivery tube containing an incompressible fluid and a viscous bone cement is provided with the viscous bone cement located within the fluoroscopy field. [¶¶0023, 0025, 0052.] Pressurizing the incompressible fluid outside the fluoroscopy field exerts pressure on the viscous material, causing the viscous material to enter the patient's body. [¶0024.]

Independent claim 78 recites a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient. A delivery device is provided and includes a container, an actuator, and a hydraulic coupling tube. [¶0052.] The container holds the viscous bone cement before the bone cement has set and also has an exit port. [¶0031.] The actuator includes an actuator vessel that contains an incompressible fluid. [¶0031.] The hydraulic coupling tube connects the actuator vessel to the container. [¶0055.] The container is positioned with respect to the patient so that the cement leaving the container through the exit port is delivered to the desired site within the patient. [¶0053.] The actuator is actuated from a location outside a field of fluoroscopic imaging while the patient is subjected to fluoroscopic imaging. [¶¶0023, 0063.] The actuation hydraulically drives a flow of viscous bone cement through the exit port to the desired injection site within the patient. [¶0057.]

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Rejection of Claims 8, 12, 20, 36-39 and 78 under 35 U.S.C. 103(a)

In the final Office Action, the Examiner rejected claims 8, 12, 20, 36-39 and 78 under 35 U.S.C. 103(a) as obvious over "Percutaneous Vertebroplasty Guided by a Combination of CT and Fluoroscopy" by Gangi et al. (cited by applicant; hereinafter "Gangi") in view of U.S. Pat. No. 4,250,887 to Dardik et al. (hereinafter "Dardik").

B. Rejection of Claims 50 and 51 under 35 U.S.C. 103(a)

In the final Office Action, the Examiner rejected claims 50 and 51 under 35 U.S.C. 103(a) as obvious over Gangi in view of Dardik as applied to claim 37 above and further in view of U.S. Pat. No. 5,431,654 to Nic (hereinafter "Nic").

C. Rejection of Claim 59 under 35 U.S.C. 103(a)

In the final Office Action, the Examiner rejected claim 59 under 35 U.S.C. 103(a) as obvious over Gangi in view of Dardik and further in view of (U.S. Pat. No. 4,494,535) to Haig (hereinafter "Haig").

D. Rejection of Claim 61 under 35 U.S.C. 103(a)

In the final Office Action, the Examiner rejected claim 61 under 35 U.S.C. 103(a) as being obvious over Gangi in view of Dardik and further in view of Voellmicke et al. (US. Pat. No. 7,008,433).

VII. ARGUMENT

Applicant traverses each of the bases for rejecting the claims.

To fully understand the claimed invention, it is necessary to appreciate the state-of-the-art at the time of Appellant's invention, which represents the background against which the claimed invention was developed.

A. The Technological Background in which the Invention was Made

The invention relates to the delivery of a viscous bone cement under fluoroscopic guidance. The invention has particular application in the field of "vertebroplasty."

A vertebra may collapse for many reasons, such as from trauma or weakening of the vertebra, as in a patient with osteoporosis. Vertebral compression fractures ("VCF") have a substantial negative impact on the patient's function and quality of life, causing discomfort and even severe pain. While the normal treatment is bed rest, patients may also receive surgery to repair the vertebra.

Vertebroplasty is a minimally invasive procedure for reducing pain caused by VCFs. The procedure is typically performed by a spine surgeon or interventional radiologist. During the procedure, the surgeon uses a biopsy needle to inject bone cement into the collapsed or fractured vertebra. The cement dries quickly and forms a support structure within the vertebra, stabilizing and strengthening it. While complications associated with vertebroplasty are relatively rare, leakage of cement outside the vertebral body can cause infection, bleeding, paralysis, heart and lung damage, and even death.

Recently, surgeons have used viscous bone cement because it is less likely to leak from the damaged vertebra. A variety of techniques have been developed to solve the mechanical problem of injecting viscous cement through a needle, but these techniques have focused on

exercising the necessary pressure directly on the patient or at a very short distance from the radiation source. [¶¶0012 et seq.]

B. The Problem Addressed by the Invention is the Delivery of Viscous Bone Cement Over a Significant Distance so as to Minimize a Surgeon's Exposure to Radiation

In the past, a surgeon performing vertebroplasty stood close to the patient and manually injected bone cement into the vertebra using a syringe. This exposed the surgeon's hands to radiation. Over time, surgeons began using viscous bone cement to minimize the risk of complications from bone cement leaking from the vertebra and into the patient's body. Surgeons injected the cement using either (1) small diameter syringes or (2) large diameter syringes and mechanical devices for increasing the pressure. Small diameter syringes can only hold a small volume of bone cement, making it necessary for a surgeon to use multiple syringes to achieve the total volume. As to the larger diameter syringes coupled with mechanical devices, the application notes that "devices of the previous technique solve only the mechanical problem of injecting the dense and viscous cement through the needle, but they are focused on exercising the necessary pressure directly on the patient or at a very short distance of the radiation source. They don't allow the operator to maintain an appropriate distance to reduce exposure to secondary radiation at acceptable levels according with the international radiological protection norms." [¶0012.]

None of the prior art devices (described in detail at ¶¶0014-20 of the application, including several used in the rejections) solve all of the problems that arise in using viscous bone cement, namely, decreasing a surgeon's exposure to radiation, generating sufficient pressure to inject the viscous bone cement, and decreasing the number of syringes required to achieve the total injection volume. The prior art that the Applicant believes to be most pertinent (the Preissman and Al-Assir references discussed below) also fails to solve the problem – these devices use mechanical leverage to push the viscous cement through a long tube. Applicant explains the problem with these devices in the application: "At present, there are commercially available devices such as pressure gun type or threaded plunger mechanisms connected directly to the needle that deposit the cement in the bone or through a high pressure short tube. ***The use***

of a long tube would have considerable resistance to the flow of the cement, favoring its solidification." [¶0009.]

It was this discovery by the Applicant that lead the Applicant away from the state of the art and toward the claimed invention.

C. The Invention Solves the Problem of Injecting Viscous Bone Cement Over a Distance by Separating the Cement Injector from the Mechanically Advantaged Actuator

In the invention, a container is provided having viscous bone cement and an exit port. An actuator having an actuator vessel containing an incompressible fluid is connected to the viscous cement container by hydraulic tubing. The viscous cement container is located with respect to the patient so that cement leaving the container through the exit port is delivered to a desired location within the patient. While at least a portion of the patient is subjected to fluoroscopic imaging, the actuator is actuated from a location outside the fluoroscopic imaging field to hydraulically drive a flow of viscous bone cement. In this way, the cement can be directly injected under fluoroscopy while the actuator, and thus the surgeon, can be safely outside the fluoroscopy field. In addition, the problem of increased resistance (and attendant premature hardening) is avoided because the cement container is located directly on the patient and the cement does not pass through a long tube.

In the primary embodiment in the specification (illustrated in Figure 1 below), the device consists of four main parts: an injecting syringe located in the vicinity of the patient, a pressure-exerting body, a hydraulic transmission tube, and a manual syringe.

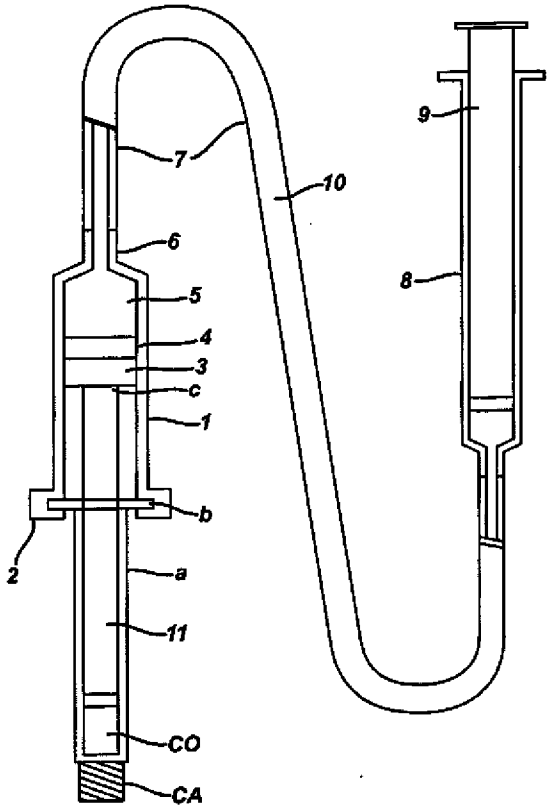


FIG. 1

While using the device, the operator depresses the hydraulic plunger 9 of the manual syringe 8. This exerts pressure on the hydraulic fluid 10 in the flexible tube and on the plunger 11 of the injecting syringe. Because of the mechanical advantage provided, this in turn exercises an increased force on the plunger. The plunger 11 exerts a force on the bone cement, causing the bone cement to be injected in the patient's vertebra through the bone biopsy needle. Once the surgeon delivers the total amount of the bone cement in the syringe, the surgeon retracts the plunger of the manual syringe and replaces the emptied syringe with a new loaded syringe.

In this way, viscous bone cement can be safely and conveniently injected under fluoroscopic guidance.

D. Rejection of Claims 8, 12, 20, 36-39 and 78 Under 35 U.S.C. 103(a)

i. Independent Claims 37 and 78 are not Obvious over Gangi in View of Dardik

There is no rationale but hindsight for combining the direct, mechanically-advantaged viscous cement injection device of Gangi with the indirect radiographic dye injection system of Dardik. The two devices are incompatible and one of ordinary skill in the art would have no motivation to combine them. Even if one of ordinary skill in the art combined the two devices, the resulting combination would not be capable of injecting viscous bone cement.

a) Examiner's obviousness rejection and rationale

In the final office action, the Examiner summarized the teachings of Gangi and Dardik. The Examiner stated:

> Concerning claims 37 and 78: Gangi discloses a method of delivering a viscous bone cement material under fluoroscopy to a site in a patient (see *Technique of Injection* section), comprising: providing a delivery device/tube having: a container (i.e. a syringe) containing a viscous bone cement (see page 82, top of the second column) prior to the bone cement having set, the container having an exit port; locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient (see *Technique of Injection* section); and while at least a portion of the patient is subjected to fluoroscopic imaging, driving a flow of viscous bone cement through the exit port to the desired injection site within the patient (see page 84, column 2, ¶ 1-3).
>
> Gangi does not specifically discloses an actuator having an actuator vessel, the actuator vessel containing an incompressible fluid; and a hydraulic coupling tube connecting the actuator vessel to the container; and actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive the flow.
>
> ***Dardik however suggests a method for delivering a viscous material (col. 3, I.64) under a radiation field 14 and capable of delivering a viscous material, namely bone cement (naturally follows from similar structure to applicant),*** to a site in a patient comprising the steps of: providing an actuator 22 having an actuator vessel, the actuator vessel containing an incompressible fluid 35; and a hydraulic coupling tube 33 connecting the actuator vessel to a container 25; and actuating the actuator from a location outside a field of radiation to hydraulically drive the flow of the viscous material from the container (Fig. 1; col. 2, I. 61 to col. 3, I. 15). Dardik suggests this method in order to reduce the radiation exposure to the surgeon (Abstract).

> ***It would have been obvious to someone of ordinary skill in the art at the time of the invention to add the actuator, hydraulic coupling tube and actuation step of Dardik to the method of Gangi in order to reduce the radiation exposure of the surgeon.*** The entire modified device of Gangi, in view of Dardik, can be considered a delivery tube in the sense that applicant's entire device can be considered a delivery tube.

In response to Applicant's arguments made on June 11, 2009, the Examiner simply repeated that "Dardik teaches a system for delivering viscous materials (col. 3; 1.64), therefore Dardik will work with viscous bone cement." The Examiner also stated that "Dardik specifically addresses the issue of reducing exposure of the surgeon to the X-rays (abstract)." The first of these statements is not true because the art expressly says that it is not true. The second of these statements points out exactly what is wrong with this rejection – closer prior art that deals directly with injecting viscous bone cement addresses precisely this problem and comes to a very different solution than what is presently claimed. It almost appears as if the Examiner has reached out to Dardik specifically for the purpose of finding non-analogous art that would not teach-away so that hindsight could be used to recreate Applicant's claimed invention.

b) The Relevant Prior Art Shows Only Different Solutions to the Problems That Are Addressed by the Claims

The Examiner relies on Gangi, a nineteen year old reference that, while it does relate to cement injection, does not address any of the problems addressed by the Applicant. To Gangi, the Examiner adds Dardik, an old dye injection reference that is not analogous and which cannot work. There is much more relevant prior art – art that the Examiner had previously cited but which now is not relied upon – that shows how persons of ordinary skill in the art actually addressed the problems of injecting viscous bone cement over a distance (a different way than that claimed – by adding a long tube at the end of the injector) and explains why systems such as Dardik's which rely on standard syringes cannot work for injecting viscous bone cement.

i) *Gangi Uses a "Pressure Regulator" to Directly Inject Cement Using Multiple Small Syringes with None of the Advantages of the Invention*

The purpose of the Gangi paper is to report on the use of fluoroscopy and computed tomography together in the performance of vertebroplasty procedures. According to Gangi, prior vertebroplasty procedures had been performed using only one type of imaging. [Gangi at 82.] Gangi, which was published in 1992, says very little about the cement injection. What it does

say is that "[f]our to 8 mL of acrylic glue were injected using a 2-mL Luer Lock syringe mounted on a pressure regulator (Meadox, Oakland, Calif) to facilitate the injection of this viscous mixture." Gangi thus had all of the possible problems with prior art devices and techniques: (1) it used small syringes so that multiple syringes had to be used; (2) there was no feature or process for keeping the surgeons out of the imaging field; and (3) the cement was sufficiently difficult to inject that a pressure regulator needed to be applied.

ii) *Dardik Does Not, and Cannot, Address the Problems that Arise in Injecting Viscous Bone Cement*

Dardik, cited by the Examiner, provides a system for the remote dispensing of angiographic dye with the key feature being maintaining surgeon "feel" while dispensing:

> The present invention provides a system whereby a surgeon can manually, ***with conventional force and feel,*** cause injection of a radiopaque dye during angiography . . . [Col. 2, lines 52-54.]

Dardik further states that in a "preferred embodiment" (in fact, it is the only embodiment, and thus the only disclosure on this topic in Dardik), Dardik uses as his driving fluid:

> a fluid such as water or oil, which might have a ***density and viscosity generally similar to that of the radiopaque injectate***. [Col. 2, lines 63 to 65]

There are three results from constructing the angeographic dye injector in the manner described by Dardick: (1) the surgeon maintains the "feel" of injecting the dye, even at a distance; (2) the dye is injected at the same rate that the surgeon works the remote plunger; and (3) the device can be made from standard tubing and syringes:

> With an apparatus as described above, ***the drive syringe and plunger are not only visually familiar to the surgeon, but they are and feel identical to the conventional injectate syringe***. Modifications may be made if necessary in the dimensions of the drive and driven syringes and intermediate hose filled with fluid, to be sure they ***simulate closely the feel of direct manual injection*** of radiopaque dye, in regard to the mass and viscosity of the dye and the force to discharge same. [Col. 3, lines 16-24.] . . . From this position the surgeon can observe both the area of vascular reconstruction and the coupled syringes; at the same time he has the ***personal control by***

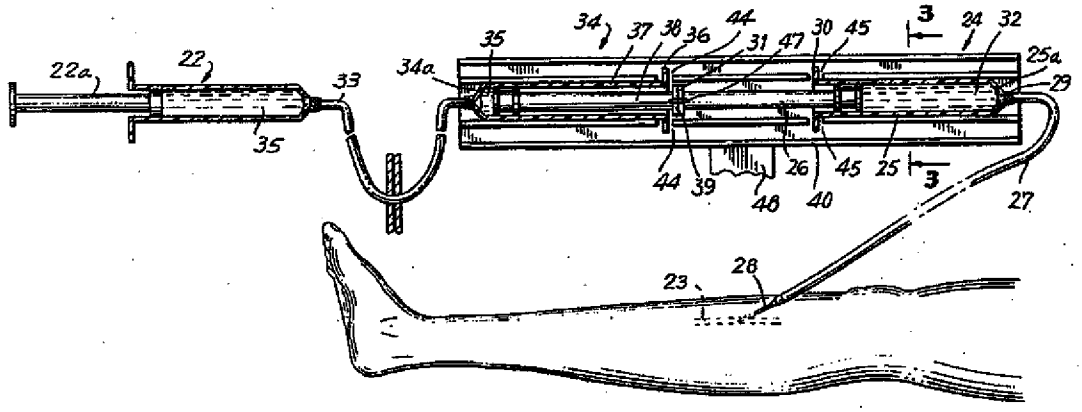
virtue of the familiar, manual "feel" of the syringe and plunger, of the fluid flow and/or resistance to the flow. [Col. 5, lines 3 to 8.]

* * *

[T]he driven plunger, when moved axially, ***will drive the injectate plunger essentially the same distance and at the same rate*** in an ideal hydraulic system. [Col. 3, lines 11-14.]

* * *

Not only does this new invention provide an apparatus that allows "manual" injection from a remote and radiation-safe location, it is extremely simple to use and inexpensive to manufacture; ***even standard syringes and tubing can be used*** . . . [Col. 3, lines 25-30.]



The system of Dardik thus will not work for vertebroplasty: because small syringes must be used for high pressure injection, Dardik would have to use multiple small syringes to inject viscous bone cement; Dardik uses a lengthy tube to the patient (which would cause viscous bone cement to resist injection and harden in the tubing); would not (because of its express teaching regarding "feel") would not apply a mechanical advantage to inject the viscous bone cement; and would lead to the use of viscous bone cement as a "hydraulic fluid" because of its express teachings regarding using a fluid of similar and viscosity to that being injected. Curing any one of these problems would violate the express teachings of Dardik..

iii) The Prior Art that Does Address the Problems Addressed by the Applicant Comes to a Different Result, and Explains Why Dardik Can't Work

Many prior art devices sought to develop bone cement injection systems that handle higher pressures and larger volumes. One such device, much more relevant to the instant invention than either Dardik or Gangi, is described in a paper and patent to Al-Assir, and in a patent to Priessman. The Al-Assir patent had previously been cited by the Examiner to reject claims in this case (March 20, 2008 Office Action), however, it has since been dropped in favor of the far less relevant Gangi reference.

The Al-Assir paper, which had also been previously cited by the Examiner in this case ("Percutaneous Vertebroplasty: A Special Syringe for Cement Injection," 21 Am. J. Neuroradiol. 159-161 (Jan. 2000)), addresses the problems of using standard syringes (such as those used by Dardik) for injecting bone cement most directly in its Summary:

> Summary: Percutaneous vertebroplasty is an effective treatment for many focal vertebral lesions. ***Methyl methacrylate is too viscous to be handled without difficulty in the conventional way*** because injection time is short. The operator is left with little time and ***must fumble with multiple syringes***. We describe a special screw-system syringe that decreases the effort needed to inject the cement. In addition, it can standardize the injection pressures and control the injected volume because the threaded plunger affords greater control of injection pressure and volume delivered than does the conventional method.

The Al-Assir patent, also cited by the Examiner during prosecution (US 6,676,664), echoes this theme, noting that "[t]he injection of cementing biomaterials is customarily carried out conventionally with standard syringes . . ." but, "the force to be applied to the plunger needs to be considerable." In other words, the hydraulic fluid delivery system of Dardik, which uses a hydraulic driver in which the driving fluid is similar in viscosity to the delivered fluid, and that employs conventional syringes, does not work well with bone cement. Al-Assir thus sets out to "improve the methods for injecting hardenable masses in vertebroplastia by facilitating the loading of the biomaterial into the interior of an injector device having special features, making it possible to work with greater injection pressure and to obtain a greater capacity of adjustment

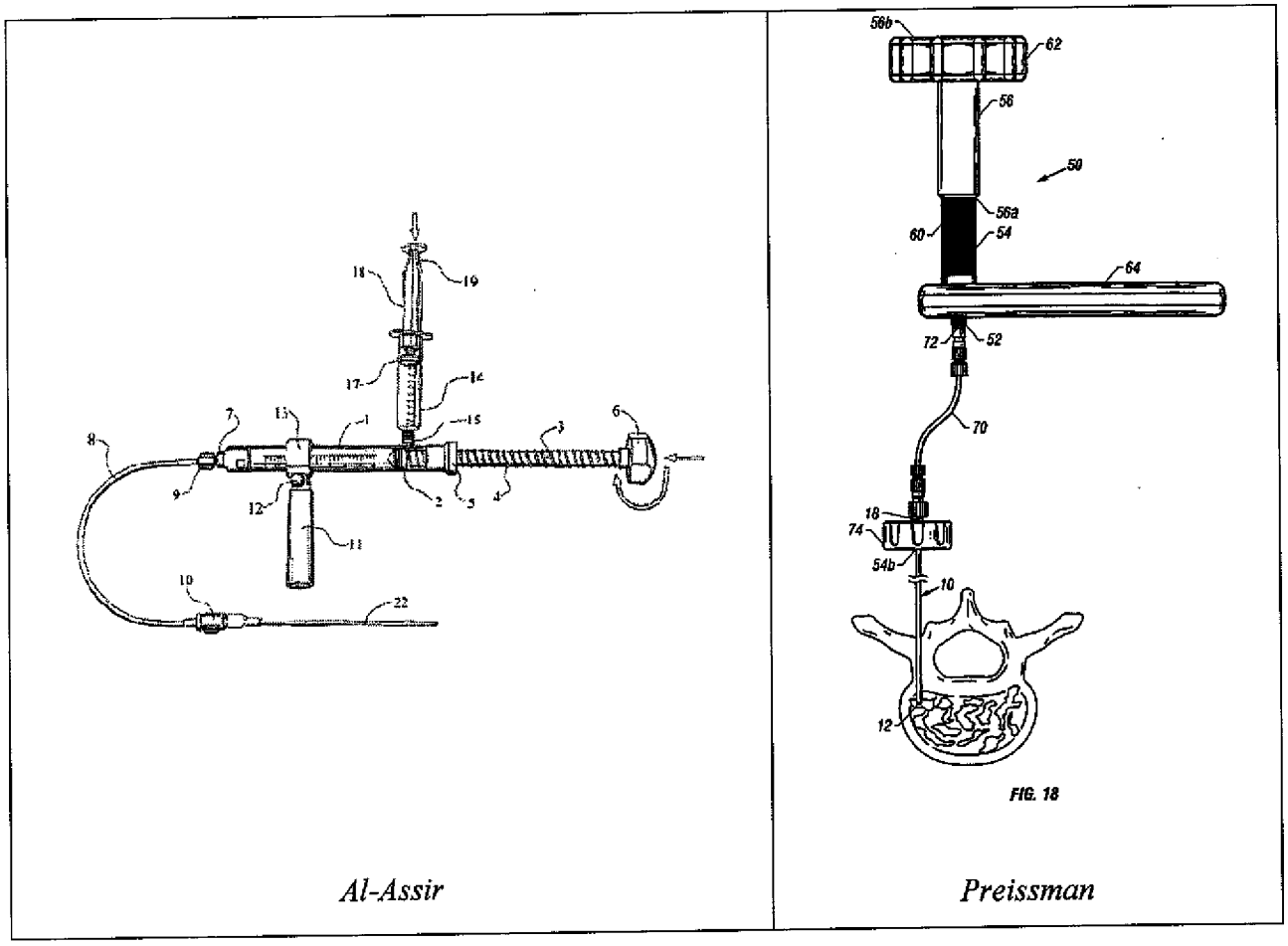
thereof . . ." Al-Assir's goal is not to improve upon Dardik, but to replace it entirely with a system that handles higher pressures and larger volumes.

U.S. 6,383,190 to Preissman, also of record in this case, makes this point even more strongly, noting the desirability of high viscosity cements and the many problems involved with injecting them through conventional syringes:

> A viscous or paste-like consistency of PMMA is generally believed to be most advantageous for performing percutaneous vertebroplasty. Such a consistency insures that the implant material stays in place much better than a less viscous, more liquid material. Leakage or seepage of PMMA from the vertebral implant site can cause a host of complications some of which can be very serious and even result in death. For example, Weil et al. reported cases of sciatica and difficulty in swallowing which were related to focal cement leakage, Radiology 1996; Vol 199, No. 1, 241-247. A leak toward the distal veins poses an even more serious risk, since this can cause a pulmonary embolism which is often fatal.
>
> * * *
>
> Because in general, ***10 cc syringes are only capable of generating pressures of about 100-150 psi***, this places a limitation on the viscosity of the PMMA that can be effectively "pushed through" the syringe and cannula and fully delivered to the implant site. Of course, ***the use of a small barrel syringe, e.g., a 1 cc syringe, enables the user to generate higher driving pressures***. For example, pressures of 1000 psi and possibly as high as 1200-1500 psi (depending upon the strength of the user and the technique) may be generated using a 1 cc syringe. ***A serious limitation with the use of a 1 cc syringe, however, is that it will not hold a large enough volume to complete the procedure in one step or "load" and must be reloaded several times*** to complete the procedure, since, on average, about 3.5 cc of implant material per side of the vertebral body are required for an implantation procedure. ***This makes the procedure more complicated with more steps, and more risky in that the polymerization of the implant material causes it to become increasingly more viscous during the additional time required for reloading***. Another problem with a 1 cc syringe is lack of control, as high pressures are generated in a "spike-like" response time and are not continuously controllable.
>
> * * *

> Thus, there is a need for a high pressure applicator that has enough storage capacity to perform a complete implantation procedure without having to reload the device in the midst of the procedure, and which is consistently controllable, for an even, constant application of pressure during delivery of the entirety of the implant material. [Col. 1, line 63 to col. 2, line 48.]

Not surprisingly, Al-Assir and Preissman both address these problems with devices that are completely different from, and incompatible with, Dardik:



Al-Assir *Preissman*

Both Al-Assir and Preissman provide mechanically-advantaged injection of bone cement through an elongated tube and/or needle. According to both, this is how one injects viscous bone cement – not using the standard syringes of Dardik.

In addition, Priessman expressly addresses the problem of keeping the surgeon's hands outside of the imaging field when imaging a patient during injection of viscous bone cement under high pressure: "The tubing 70 enables both the applicator 50, and thus the user's hands to

be distanced from the radiographic field or other viewing field, which is advantageous both for safety purposes as well as improving the procedure."

There can be no doubt that this art is much more relevant to the present claims than the art cited by the Examiner – and this art takes a completely different approach to the problems addressed by the Applicant than the Examiner's hindsight recreation based on less relevant, non-analogous art. Priessman and Al-Assir solve the problems involved in injecting viscous bone cement at a distance by adding tubing at the end of the high pressure syringe. Applicant discovered that this approach causes increased resistance in the tube and leads to the cement hardening there. Accordingly, Applicant developed a different and better solution that is now claimed. One that no person of skill in the art would predict from Gangi, or Dardik, or their combination.

c) *One of Ordinary Skill in the Art Would not Combine Gangi and Dardik: Gangi Uses Direct, Mechanically-Advantaged Injection through an Elongated Needle while Dardik uses Indirect Injection with Conventional Syringes*

According to the Examiner, it would have been obvious to someone of ordinary skill in the art at the time of the invention to substitute the steps and apparatus of Dardik et al. into the method of Gangi in order to reduce the surgeon's radiation exposure. The Examiner's rationale for combining the two references is directly contrary to the art. Prior art devices reduced a surgeon's exposure to X-rays by using the length of the high pressure tubing and stylet to move the surgeon away from the radiation and employed pressure regulators to generate adequate pressure to inject viscous bone cement. This is completely different than the device of Dardik, which indirectly injects radiographic dye (which is much less viscous than bone cement) using conventional syringes.

"The patent statute provides that '[a] person shall be entitled to a patent unless' any of the § 102 or 103 bars applies," *In re Soni*, 54 F.3d 746, 749-50 (Fed. Cir. 1995). The Examiner "bears the burden of establishing a prima facie case of obviousness." *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995). In order to make out such an obviousness rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art to the claims. As the court explained in *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006),

"[R]ejections on obviousness grounds *cannot be sustained by mere conclusory statements*; instead, there *must be some articulated reasoning with some rational underpinning* to support the legal conclusion of obviousness." emphasis added. Without such rational underpinning, the Examiner easily falls prey to improper hindsight reasoning:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ***ex post* reasoning**. *See Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'".)

KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, the Examiner has committed hindsight bias by using the independent claims as a roadmap for formulating the §103(a) rejection. In applying hindsight bias, the Examiner has overlooked why one of ordinary skill in the art would ***not*** combine Gangi and Dardik. The prior art teaches away from using an indirect injection system to reduce a surgeon's exposure to radiation because viscous bone cement is extremely difficult to inject using conventional syringes.

The Federal Circuit has commented on the requirements for a reference to teach away:

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or ***would be led in a direction divergent from the path that was taken by the applicant***. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the ***line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant***.

In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994). emphasis added. Both Al-Assir and Preissman provide direct, mechanically-advantaged injection of bone cement through an elongated tube and needle or both. According to both references, bone cement is most effectively injected through an elongated tube and needle – not using the standard syringes of Dardik. Not surprisingly, Al-Assir and Preissman both address these problems with devices that are completely different from, and incompatible with, Dardik.

d) Even if the Board Finds that there is Motivation to Combine the Two References, Modifying Gangi by Adding the Proposed Features of Dardik would Expressly Render the Device Incapable of Delivering Viscous Bone Cement – the Prior Art Teaches Away from Doing This

The combination of the two references corresponding to the Examiner's rejection in the Final Office Action would result in a device having: (1) a conventional syringe, (2) a tube filled with hydraulic fluid of similar viscosity to bone cement, and (3) an injection device located within eyesight of the surgeon so that the cement leaving the device is delivered to a desired injection site within the patient through a tube.

The Examiner relies on Dardik to teach an actuator vessel containing an incompressible fluid, a hydraulic coupling tube connecting the actuator vessel to the container, and actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive the flow. In Dardik, the actuator vessel is a conventional syringe 22. Under Dardik, the surgeon is able to manually depress the syringe 22 to inject the radiopaque dye because radiopaque dye is much less viscous than bone cement and does not harden overtime.

One of ordinary skill in the art would not combine the actuator and hydraulic fluid system of Dardik with the bone cement injection device of Gangi because the combination could not inject bone cement. Although the Examiner's rejection is based on the premise that Dardik can inject viscous bone cement,[1] Dardik will not work with viscous bone cement. The Al-Assir paper cited by the Examiner ("Percutaneous Vertebroplasty: A Special Syringe for Cement Injection," 21 Am. J. Neuroradiol. 159-161 (Jan. 2000)) puts this most directly in its Summary:

> Summary: Percutaneous vertebroplasty is an effective treatment for many focal vertebral lesions. ***Methyl methacrylate is too viscous to be handled without difficulty in the conventional way because injection time is short. The operator is left with little time and must fumble with multiple syringes.*** We describe a special screw-system syringe that decreases the effort needed to inject the cement. In addition, it can standardize the injection pressures and control the injected volume because the

[1] The Examiner states that Dardik can inject a viscous material, so it must be able to inject a viscous bone cement. The Examiner provides no basis for this position – Applicant presumes that because Dardik injects a material having similar characteristics to water, and because water has a measurable viscosity, that the Examiner considers it to be a viscous material. The claims, however, recite viscous bone cement, a material that is demonstrably different than water.

> threaded plunger affords greater control of injection pressure and volume delivered than does the conventional method.

Contrary to the Examiner's assertions, the recited combination of Gangi and Dardik would not be capable of delivering viscous bone cement. Conventional syringes cannot inject viscous bone cement. Likewise, conventional syringes cannot inject hydraulic fluid that has a viscosity similar to bone cement. The only possible way this device could work is by employing a pressure regulator to drive the bone cement through the syringes (thus requiring multiple small syringes to inject). One of ordinary skill in the art would have no motivation to make such a substitution because this would leave in place all of the problems that Applicant was trying to avoid by making this invention. The prior art tells us that this combination will not work, and we should believe it.

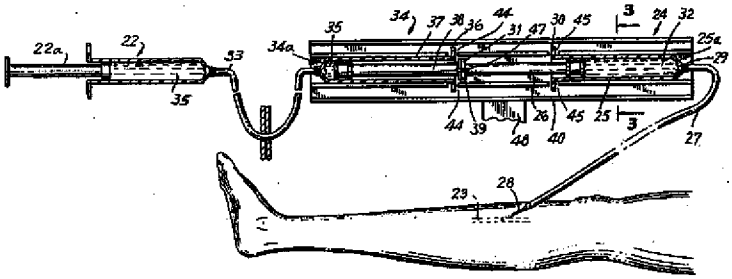
e) Dardik is Non-Analogous Prior Art

As the Federal Circuit made clear recently in *In re Klein* (Docket No. 2010-1411; decided June 6, 2011), a "reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention." [Page 7, citations omitted.] "'Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.' *Bigio*, at 1325." [Id.] "'A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.' Clay, 966 F.2d at 659." [Id.]

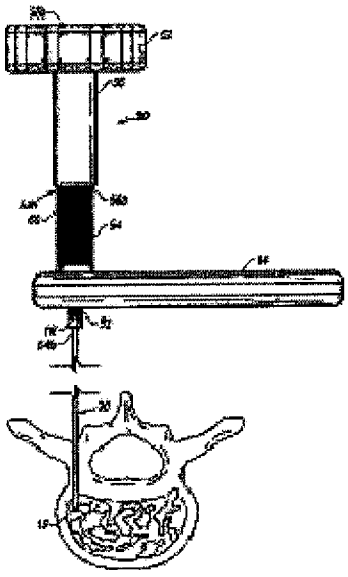
Here, Dardik deals with diagnostic procedures that involve the injection of dye into the patient's blood stream. The inventors are exclusively interested in a therapeutic procedure in which a viscous bone cement is injected into a patient. It is the fact of the viscous bone cement that drove both the problem the inventors addressed as well as their solution. Dardik deals in a different field of endeavor, and no person of ordinary skill in the art would logically look to a device that injects fluids having the consistency of water in order to inject viscous bone cement.

ii. Dependent Claim 20 is Separately Patentable over the Rejection

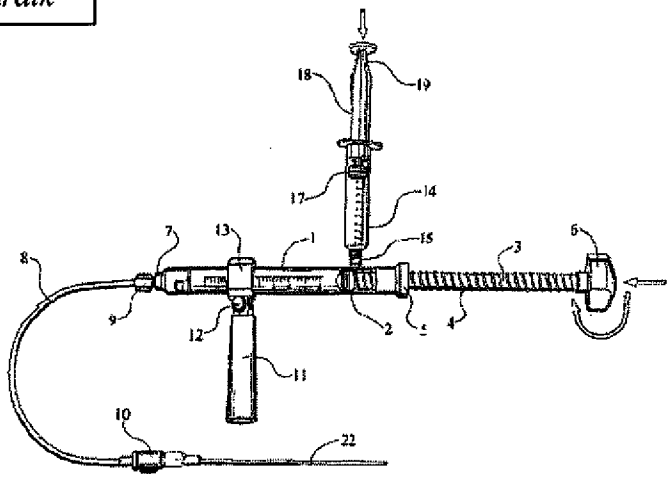
Dependent claim 20 is separately patentable over the rejection because it recites "an injection needle connected to the exit port for delivery of the viscous material to the desired injection site". As shown, Dardick has a flexible extension tube 27 between its "exit opening" and its "needle." Al-Assir (8) and Preissman (70) also have flexible tubes connecting the "exit port" to the "injection needle." Accordingly, all of these references (all of the references that deal with injecting at a distance), do so by using the very tube that Applicant discovered resists the injection of viscous bone cement and causes premature hardening. Accordingly, any combination using these references for teaching injection at a distance cannot make out a prima facie rejection against claim 20.



Dardik

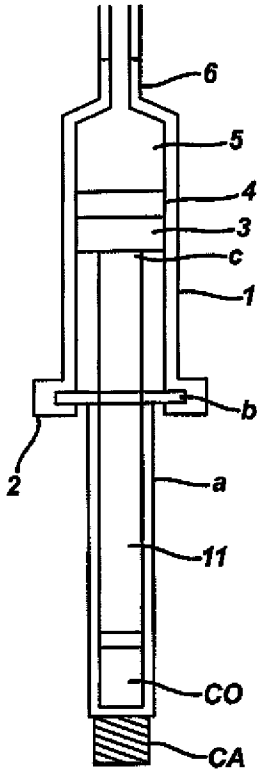


Preissman



Al-Assir

The teachings of these references are inconsistent with claim 20, which requires that the injection needle is *connected* to the exit port for delivery of the viscous material to the injection site. A portion of Figure 1 is reproduced at right and shows the direct, threaded connection between the syringe a (which injects the bone cement) and the bone needle CA. Applicants recognized the problem with the prior art devices, namely that the pressure drop of high viscosity bone cement through extension tubes causes its own problems. Applicant thus proposed a solution that is different from the prior art references, alone or combined, and by separating the actuator, manual syringe 8, from the syringe a using a tube filled with hydraulic fluid ***and*** by having the bone needle extend directly from the exit opening. Applicant's solution is different from and better than the prior art.



E. Rejection of Claims 50 and 51 Under 35 U.S.C. 103(a)

Dependent claim 50 is dependent upon claim 37 and further recites applying ***force amplification*** on the incompressible fluid. Claim 51 depends on claim 50 and further recites applying force amplification on the incompressible fluid by *mechanical advantage*.

The Examiner states:

> Gangi, in view of Dardik, fairly suggests the claimed invention but not specifically force amplification. Nic, however, discloses that during injection of bone cement it may be necessary to amplify the force applied as the bone cement becomes less flowable (col. 10, l. 20-34). It would have been obvious to someone of ordinary skill in the art at the time of the invention to amplify the force in the modified invention of Gangi, in view of Dardik, if the bone cement becomes less flowable. Amplifying force using mechanical advantage was a known method at the time of the invention. Therefore, claim 51 would have been obvious because amplifying force using mechanical advantage was a part of the ordinary capabilities of one skill in the art.

i. Claims 50 and 51 are not obvious at least because they depend from a patentable claim

For the reasons previously stated, claim 37 is non-obvious. Therefore, claims 50 and 51 are not obvious at least because they depend from a patentable claim.

ii. Claim 51 is separately patentable because Nic only identifies the problem of hardening bone cement and one of ordinary skill in the art, after looking at the three references, would not pursue the particular solution of the claims

Claim 51 is separately patentable because Dardik teaches away from the recited combination by expressly discouraging the use of mechanical advantage. Dardik injects radiopaque dye that is much less viscous than bone cement. Therefore, in Dardik there is no need to amplify the force over the injection time because the viscosity of the fluid stays the same. Unlike cement, radiopaque dye does not harden over time. While using the Dardik device, the surgeon manually depresses a syringe that has a similar look and feel as a conventional syringe filled with radiographic dye. This injects the dye at the same rate that the surgeon works the remote plunger. This is the inventive aspect of Dardik because it allows the surgeon to maintain the same "feel" of injecting dye directly into a patient while remaining at a safe distance from the X-rays.

As previously argued, the combination of Gangi and Dardik is not capable of injecting viscous bone cement. Similarly, the combination of Gangi and Dardik and Nic is not capable of injecting viscous bone cement.

F. Rejection of Claim 59 Under 35 U.S.C. 103(a)

Claim 59 depends from claim 39 and further recites cooling the bone cement to delay its hardening. In the Final Office Action, the Examiner states:

> Gangi, in view of Dardik failed to teach cooling the bone cement to delay its hardening.
>
> Haig teaches cooling the bone cement to delay its hardening (col. 2, lines 18-22).
>
> It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to cool the cement in view of Haig for insuring maximum length of the liquid phase of the cement necessary for its injection.

For the reasons previously stated, claim 37 is non-obvious. Therefore, claim 59 is not obvious at least because it depends from a patentable claim.

G. Rejection of Claim 61 Under 35 U.S.C. 103(a)

Claim 61 depends from claim 37 and further recites delivering 10 cc of bone cement to a bone. The Examiner states:

> Gangi, in view of Dardik failed to teach delivering 10 ml of cement to a bone.
>
> Voellmicke teaches delivering 10 ml of cement to a bone (col. 1, lines 5-14).
>
> It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to deliver up to 10mI of cement in view of Voellmicke for effectively repair a bone fraction and providing an effective fixation system.

For the reasons previously stated, claim 37 is non-obvious. Therefore, claim 61 is not obvious at least because it depends from a patentable claim.

VIII. CONCLUSION

Applicant recognized the advantage of moving the injection syringe close to the patient and coupling the injection syringe to a manual syringe using a flexible tube filled with hydraulic fluid. Applicant proposed a solution that is much different from the prior art references, alone or in combination, by separating the actuator (manual syringe) from the injecting syringe. This configuration decreases the surgeon's radiation exposure and allows the surgeon to control the speed and pressure of the injection (decreasing the risk of patient complications). This is different from and far better than the prior art. Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which were required to be filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-890.

Dated: July 25, 2011

Respectfully submitted,

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CLAIMS APPENDIX

1-7. (Canceled)

8. (Previously Presented) The method of claim 78, wherein the actuator comprises a hydraulic press.

9-11. (Canceled)

12. (Previously Presented) The method of claim 78, wherein the hydraulic tube is flexible.

13-19. (Canceled)

20. (Previously Presented) The method of claim 78, further comprising an injection needle connected to the exit port for delivery of the viscous material to the desired injection site in the patient.

21-35. (Canceled)

36. (Previously Presented) The method of claim 37, further comprising a separator sized to move within the inner bore of the tube while separating the viscous material from the incompressible fluid.

37. (Previously Presented) A method of delivering a viscous material under fluoroscopy to a site in a patient comprising the steps of:

a) providing a delivery tube containing an incompressible fluid and a viscous material, wherein the viscous material is located within the fluoroscopy field and the viscous material comprises bone cement; and

b) pressurizing the incompressible fluid outside the fluoroscopy field to exert pressure on the viscous material.

38. (Previously Presented) The method of claim 37 wherein the hydraulic tube is flexible.

39. (Previously Presented) The method of claim 37 wherein the step of pressurizing the incompressible fluid, comprises using a linear actuator.

40-49. (Canceled)

50. (Previously Presented) A method according to claim 37, further comprising applying force amplification on the incompressible fluid.

51. (Previously Presented) A method according to claim 37, further comprising applying force amplification on the incompressible fluid by mechanical advantage.

52-58. (Canceled)

59. (Previously Presented) A method according to claim 37, comprising cooling said bone cement in a manner sufficient to delay its hardening.

60. (Withdrawn) A method according to claim 37, further comprising replacing a cement chamber during a single medical procedure.

61. (Previously Presented) A method according to claim 37, further comprising delivering 10 cc of bone cement to a bone.

62-77. (Canceled)

78. (Previously Presented) A method of delivering a viscous bone cement material under fluoroscopy to a site in a patient, comprising:

providing a delivery device having:

a container containing a viscous bone cement prior to the bone cement having set, the container having an exit port;

an actuator having an actuator vessel, the actuator vessel containing an incompressible fluid; and

a hydraulic coupling tube connecting the actuator vessel to the container;

locating the container with respect to the patient so that cement leaving the container through the exit port is delivered to a desired injection site within the patient; and

while at least a portion of the patient is subjected to fluoroscopic imaging, actuating the actuator from a location outside a field of fluoroscopic imaging to hydraulically drive a flow of viscous bone cement through the exit port to the desired injection site within the patient.

EVIDENCE APPENDIX

No evidence has been submitted.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

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